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| 10/792,214 | 03/04/2004 | Sheng-Ping Zhong | 12013/62704 | 4161 |

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KENYON & KENYON LLP
1500 K STREET N.W.
SUITE 700
WASHINGTON, DC 20005

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| EXAMINER |
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PREBILIC, PAUL B

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| ART UNIT | PAPER NUMBER |
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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/792,214 | ZHONG, SHENG-PING | |
| | Examiner | Art Unit | |
| | Paul B. Prebilic | 3774 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26,36,37,42 and 43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26,36,37,42 and 43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 29, 2008 has been entered.

Election/Restrictions

Claims 22-25 and 40 were withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the communication filed February 6, 2006. **These claims were cancelled by the amendment filed March 26, 2007.**

Terminal Disclaimer

The terminal disclaimers filed on March 26, 2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patents 6,197,051 and 6,723,121 have been reviewed and accepted. The terminal disclaimers have been recorded.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 26, 36, 37, 42, and 43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The meaning of a "functional group" as used in the specification and claims was not adequately described; see the attached definition of "groups" from Hawley's Condensed Chemical Dictionary. Referring to claim 36, "aziridine" is an imine ring structure of ethylene imine so it is not clear how it can be a polyfunctional molecule in that it has only three elements in the entire molecule; see the attached dictionary definition for an aziridine. Not all of the elements of the aziridine molecule are known functional groups. For this reason, it is not clear what is meant by "functional groups." It is noted that pages 8 and 9 of the specification mentions a polyfunctional "aziridine" containing three aziridine moieties, but this molecule is not an aziridine in the ordinary sense. Moreover, the specification does not give a special definition to the term "aziridine" in that it does not redefine it in a clear, deliberate and precise manner.

"One purpose for examining the specification is to determine if the patentee has limited the scope of the claim.' . . . For example, an inventor may choose to be his own lexicographer if he defines the specific terms used to describe the invention 'with reasonable clarity, deliberateness, and precision.' Such as definition may appear in the written description" Teleflex, Inc. v. Ficosa No. Am. Corp., 63 USPQ2d 1374, 1381 (Fed. Cir. 2002)

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Since no special definition has been established, the usage of “functional groups” and “aziridine” conflicts with the ordinary definition of these terms.

It is noted that the present claims only require “three or more functional groups per molecule” (see claim 26), and the claim does not specify that the “functional groups” are crosslinking functional groups or whether the “molecule” is the agent molecule.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26, 36, 37, 42 and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are indefinite because it is not clear from the record how to interpret “functional groups” and thus, what constitutes a “polyfunctional cross-linking agent.”

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 26, 37 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Shults et al (US 4,994,167). Shults anticipates the claim language

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where BAYBOND 123 (see column 13, lines 11-46 of Shults) is a polycarbonate-polyurethane composition that is equivalent to Applicant's Bayhydrol 123 (see page 8, lines 1-3 of the specification) and wherein the organic acid functional groups are the carboxylate groups on the polymer backbone; see column 13, lines 11-27. On column 13, lines 52-55, Shults states that a crosslinking agent is added to the polymer to make the polymer. It appears that the claims do not preclude the n-methyl-2-pyrrolidone contained in each of these dispersions; see columns 13 and 14 of Shults. The coating composition contains an excess of polyfunctional crosslinking agent as claimed because an excess of cross-linking agent is not required just enough to crosslink some of the functional groups and provide functional groups capable of reacting with a bioactive agent. The bioactive agent is not positively required. The carbodiimide crosslinking agent of Shults has at least three functional groups to the extent required by the present claim language because aziridine (a smaller molecule of three elements) is claimed as having three or more functional groups; see claim 36.

With regard to claim 43, Shultz teaches the reaction of the coating mixture (see column 13, lines 52-63) with the bioactive agent polyvinylpyrrolidone so the limitation of the claim is considered met.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which

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said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shults et al (US 4,994,167) in view of Zhong (EP 0728487) or Dutta et al (US 5,528,830). Shults discloses using various crosslinking agents but not crosslinking agents of aziridine as claimed. However, Zhong (see the abstract) or Dutta (see column 1, lines 25-35 and column 11, lines 18-25) teach that it was known to utilize aziridine as a crosslinking agent in the medical coating art. Therefore, it is the Examiner's position that it would have been obvious to substitute aziridine as the crosslinking agent of Shults in that it is a known equivalent.

Claim 42 is rejected under 35 U.S.C. 103(a) as obvious over Shults et al (US 4,994,167) in view of Nishimura et al (US 4,888,285) or Compere et al (US 4,287,305) or Guire (US 4,979,959). One could reasonably interpret the claims are requiring a molar excess with respect to all organic acid functional groups. However, the prior art, as exemplified by Nishimura (see column 6, line 4 et seq.) or Compere (see the column 3, lines 1-18 and the abstract) or Guire (see column 12, line 43 et seq. or column 13, line 32 seq.), knew to use a molar excess of crosslinking agent or reactant in order ensure that the reaction went to as close to 100% completion as possible. Therefore, it is the Examiner's position that it would have been obvious to utilize an excess of crosslinking agent with respect to all organic acid functional groups of Shults in order to ensure that the reaction goes to as close to 100% completion as possible or for the reasons that Nishimura, Compere, or Guire utilize the same.

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Response to Arguments

Applicant's arguments with respect to claims 26, 36, 37, and 42-43 have been considered but are moot in view of the new interpretation of the claim language precipitated by the amendments thereto.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Paul Prebilic/
Paul Prebilic
Primary Examiner
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